

REMARKS

Claims 1, 3-5, 17 and 19-24 are pending and under examination. Withdrawn claims 10-16 and 18 are being maintained of record pending the filing of a divisional application.

By this Amendment claims 1, 22 and 24 have been amended to recite a "suspension". Support for this amendment may be found on page 10, lines 12-13 ("The suspended nature of bone marrow or PBPC populations . . ."). Claim 24 has also been amended by changing "harvested cells of transplant cells" to the more appropriate "harvested transplant cells". Applicants respectfully submit that the amendments are fully supported by the disclosure and do not raise an issue of new matter. Entry of the amendments is respectfully requested.

IS THE REJECTION FINAL OR NON-FINAL?

On page 1 of the September 30, 2005 Office Action, Box 2a ("This action is FINAL") is checked. Yet the Office Action does not contain Form Paragraph 7.39, which paragraph usually concludes final rejections (MPEP §706.07, Rev. 4, October 2005, p. 700-80). Moreover, PAIR (visited January 30, 2006) indicates that the September 30, 2005 Office Action is non-final. The undersigned respectfully requests clarification as to whether the September 30, 2005 Action is "final" or "non-final".

INFORMATION DISCLOSURE STATEMENT

At the request of the Examiner, on September 27, 2005 applicants submitted a form PTO-1449 listing the journal articles that had been cited and submitted in the August 1, 2005 Amendment. Applicants respectfully request that a copy of the September 27, 2005 Form PTO-1449 initialed by the Examiner be returned to applicants with the next Action.

DOUBLE PATENTING

The provisional obviousness-type double patenting rejections of claims 1-2 and 6-9 have been maintained. Claims 1-2 and 6-9 have been rejected as allegedly being unpatentable over claim 35 of copending Application No. 09/664,444, claim 18 of copending Application No. 10/743,639, and claim 18 of copending Application No. 10/743,649, in all three cases in view of Weber et al. and Rummel et al. As previously stated, applicants will consider filing a terminal disclaimer when otherwise allowable subject matter is indicated.

CLAIMS ARE NONOBVIOUS

Claims 1, 3-5, 17 and 19-24 have been rejected under 35 U.S.C. §103 as allegedly being unpatentable over WO 99/18799 (Roberts, et al.) and Wolff, et al., Human Gene Ther. 1998, Vol. 9, pp. 2277-2284 (Wolff, et al.). The rejection is respectfully traversed.

The Office Action cited Roberts as teaching “that the replication competent . . . virus VSV is able to kill the tumor cell line in vitro and reduce a neoplasm in the animal implanted tumor model via the oncolytic mechanism exhibited by VSV (See page 8-9, Table 1 on page 22 and claims 1, 116 and 117).” (September 30, 2005 Office Action, para. 11). The rejection acknowledged that “Roberts et al. do not teach an ex vivo method directed to clean the contaminated cancer cells in the mixture of the autograft stem cells using oncolytic VSV.” (September 30, 2005 Office Action, para. 11).

Wolff is cited as teaching “that the specific elimination of contaminated breast cancer cells during autograft cancer therapy is very important” and as suggesting “that ADCMV-Cd/5-FC [recombinant adenovirus carrying prodrug-converting cytosine deaminase and 5-fluorocytosine] may be safely and efficiently applied to purge autografts from breast cancer patients.” (September 30, 2005 Office Action, para. 12). The rejection concluded

that “it would have been obvious . . . to adapt an *ex vivo* oncolytic method as suggested by Wolff et al. to purge autografting hematopoietic cells with oncolytic VSV taught by Roberts et al. . . .” (September 30, 2005 Office Action, para. 11).

Based on the teachings of Roberts and Wolff the person of ordinary skill in the art would not have had a reasonable expectation that VSV could be used successfully to selectively purge neoplastic cells from an *ex vivo* suspension of normal hematopoietic cells and neoplastic cells. Example 26 of Roberts (page 73) shows the results of an *in vitro* experiment that tests the ability of VSV to kill tumorigenic and non-tumorigenic cells. In Example 26 VSV was tested against an adherent monolayer of tumorigenic cells separately and an adherent monolayer of non-tumorigenic cells separately. Example 26 did not test VSV against a mixture of tumorigenic cells and non-tumorigenic cells in a suspension. Although Roberts teaches the use of VSV against neoplastic cells *in vivo*, the *in vivo* environment does not replicate the environment in which neoplastic and normal cells are mixed together in the form of a suspension. The person of ordinary skill in the art would not have extrapolated these teachings of Roberts to an *ex vivo* suspension of neoplastic and normal cells.

Wolff utilizes an adenovirus to deliver a transgene into tumor cells. It is the expression of the transgene that is responsible for the efficacy of the Wolff method. The person of ordinary skill in the art would not have extrapolated the Wolff method to the very different strategy of utilizing a different virus for the anti-tumor activity of the virus rather than as a vector for delivering an expressible transgene. Accordingly, the combination of Wolff with Roberts would not have provided the reasonable expectation of success needed to sustain an obviousness rejection.

CONCLUSION

In view of the amendments and the preceding remarks, it is believed that the obviousness rejection has been overcome. Reconsideration and withdrawal is respectfully requested.

It is believed that no fee, other than the extension of time fee, is required in connection with the filing of this Amendment. If any fee is required, the Commissioner is hereby authorized to charge the amount of such fee to Deposit Account No. 50-1677.

Respectfully submitted,



Lewis J. Kreisler

Reg. No. 38522

Attorney for Applicant(s)

930 Clopper Road
Gaithersburg, MD 20878
Phone: (240) 631-2500 x3276
Facsimile: (240) 683-3794